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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,267	08/22/2003	Kathryn Lindsay Ball	CCI-007USDV	9453

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,267

Applicant(s)

BALL ET AL.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-8, 11 and 12 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Pursuant to the directives of the response filed 3/3/06, claims 1-8, 11-12 have been amended, and claims 9-10 cancelled. Claims 1-8, 11-12 remain pending. Applicants' election of Group I is acknowledged.

Also acknowledged are the species elections:

- a) the G1 cdk is cdk4;
- b) the "substance" referred to in line 2 of claim 1 is a single pure compound;
- c) [not applicable];
- d) Rb phosphorylation as the specific "activity" of the G1 cdk that is to be inhibited.

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The claims are now subject to further restriction, as set forth below.

Restriction to one of the following inventions is required under 35 U.S.C. §121 (the numbering begins with "III" to avoid conflict with the previous numbering system):

III. Claims 1-5, 8, 11-12, drawn to a method of inhibiting an activity of a G1 cdk comprising the use of a "substance that includes a peptide", and wherein a carrier molecule is neither suggested nor required.

IV. Claims 6-7, drawn to a method of inhibiting an activity of a G1 cdk comprising the use of a "substance that includes a peptide", and wherein the peptide is coupled to a carrier molecule.

V. Claim 12, drawn to a method of determining whether, and to what degree, cell cycle arrest may have occurred.

The claimed inventions are distinct.

Groups III and IV are distinct. It is entirely possible that the genus of claim 1 is novel, but that, at the same time, the invention of claims 6-7 is not. It may be the case that applicants are the first to discover that an activity of a G1 cdk can be inhibited when contacted with a peptide that consists of 40 amino acids or less.

But that does not mean that claim 6 is necessarily novel. Claim 6 could be interpreted to include proteins of any molecular weight. It may well be the case that it was known in the art that any of several proteins could inhibit the activity of a G1 cdk, and which proteins contain the subsequence identified in claim 1.

Thus, if the nature of the "carrier molecule" is not specified, novelty of the Group III claims will not necessarily extend to the group IV claims.

Group V is distinct from Groups III and IV in that Group V requires assaying for mitotic activity. However, in the event that Group III is elected, and claims therein found allowable, it would be appropriate to revisit the matter of restriction between Groups III and V.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that Group III is chosen for initial examination, election of each of the following is required:

- (a) one of the following: (i) the elected substance is identical to the peptide of 40 amino acids (or less) that is described in claim 1, or (ii) the elected substance contains at least one atom that is not present in the peptide of 40 amino acids (or less) that is described in claim 1;
- b) a specific substance that falls within the scope of claim 1, in which the peptide (of 40 amino acids or less) is specifically identified;

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In the event that Group IV is chosen for initial examination, election of each of the following is required:

- (a) one of the following: (i) the elected substance is identical to the peptide of 40 amino acids (or less) that is described in claim 1 and to which the carrier molecule is coupled, or (ii) the elected substance contains at least one atom that is not present in the peptide/ carrier molecule conjugate that is described in claim 6;

b) a specific substance that falls within the scope of claim 1, in which the peptide (of 40 amino acids or less) is specifically identified and the carrier molecule is specifically identified.

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In the event that Group V is chosen for initial examination, election of each of the following is required:

(a) one of the following: (i) the elected substance is identical to the peptide of 40 amino acids (or less) that is described in claim 1, or (ii) the elected substance contains at least one atom that is not present in the peptide of 40 amino acids (or less) that is described in claim 1;

b) a specific substance that falls within the scope of claim 1, in which the peptide (of 40 amino acids or less) is specifically identified;

c) a specific cell type on which the cycle arrest assay is to be conducted.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. , 103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read "David Lukton". The signature is written in a cursive, flowing style.

DAVID LUKTON, PH.D.
PRIMARY EXAMINER